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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,747	02/08/2002	Da Gong Wang	PTZ-033	2859

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,747	WANG ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *49-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 49-95 are pending in the application and are currently under prosecution.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Claim 49 link(s) inventions 1-36. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 49. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 1-18, claims 49-50, 52-62, drawn to a method for detecting abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma, comprising detecting the protein level of Pin1, classified in class

435, subclass 7.1. A method detecting each of abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Groups 19-36, claims 49, 51-56, 63-64, drawn to a method for detecting abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma, comprising detecting the mRNA level of Pin1, classified in class 435, subclass 6. A method detecting each of abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Claim 65 link(s) inventions 37-72. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 65. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional

application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 37-54, claims 65-66, 68-72, 75, drawn to a method for determining stage of cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or in cancer of the pancreas, lymphoma, lipoma, or liposarcoma, comprising detecting the protein level of Pin1, classified in class 435, subclass 7.1. A method detecting stage of each cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or of cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Groups 55-72, claims 65, 67-68, 73-77, drawn to a method for determining stage of cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or in cancer of the pancreas, lymphoma, lipoma, or liposarcoma, comprising detecting the mRNA level of Pin1, classified in class 435, subclass 6. A method detecting stage of each cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or of cancer

of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Claim 78 link(s) inventions 73-108. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 78. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 73-90, claims 78-79, 81-85, 92-93, drawn to a method for detecting the efficacy of a treatment of abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma, or a method for determining the likelihood of responding to treatment, comprising detecting the protein level of Pin1, classified in class 435, subclass 7.1. A method detecting the efficacy of or the likelihood of responding to treatment of each of abnormal cell growth in

rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Groups 91-108, claims 78, 80-81, 86-87, 92-93, drawn to a method for detecting the efficacy of a treatment of abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma, or a method for determining the likelihood of responding to treatment, comprising detecting the mRNA level of Pin1, classified in class 435, subclass 6. A method detecting the efficacy of or the likelihood of responding to treatment of each of abnormal cell growth in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Group 109, claims 88-89, 91, drawn to a kit comprising an antibody to Pin1.

Group 110, claims 88, 90-91, drawn to a kit comprising a Pin1 DNA probe.

Claim 94 link(s) inventions 111-146. The restriction requirement among/between the linked inventions is subject to the nonallowance of the linking claim(s), claim 94. Upon the allowance of the linking claim(s), the restriction

requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 111-128, claims 94-95, drawn to a method for treating cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma, comprising administering an inhibitor of Pin1 protein, classified in class 514, subclass 2. A method treating each of the cancers in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Groups 129-146, claims 94-95, drawn to a method for treating cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma, comprising

administering an inhibitor of Pin1 polynucleotide, classified in class 514, subclass 44. A method treating each of the cancers in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma constitutes a single distinct invention.

Groups 109-110 are further subject to election of a single disclosed species.

Claims 88-91 are generic to a plurality of disclosed patentably distinct species comprising a test sample from cancer in rectum, mouth, central nervous system, endometrium, head, neck, parotid tissue, brain, gall bladder, esophagus, thyroid, parathyroid, uterus, adrenal tissue, or cancer of the pancreas, lymphoma, lipoma, or liposarcoma.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-108, 118-146 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions 109, 110 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups (1-18, 37-54, 73-90, 118-128) and 109 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using

the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups (19-36, 55-72, 91-108, 129-146) and 110 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide can be used in a materially different process such as for making a vector.

The inventions of Groups (1-18, 37-54, 73-90, 118-128) and 110 are not related, because the methods of groups (1-18, 37-54, 73-90, 118-128) do not use the DNA probe of group 110.

The inventions of Groups (19-36, 55-72, 91-108, 129-146) and 109 are not related because the methods of groups (19-36, 55-72, 91-108, 129-146) do not use the antibody of group 109.

The species are distinct because they are different cancers with different etiology and characteristics.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different

classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention, including the elected species if applicable, to be examined even though the requirement could be traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

August 06, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER